

REMARKS

Status of Claims

Claims 1-35 and 37-44 are pending in the application and rejected. Claims 1, 3 and 37 have been amended. No new matter has been added. Support for the amendments can be found in the original application as filed on August 4, 1998. In particular, support can be found at page 1, lines 3-8 and 17-18.

Rejection Under 35 U.S.C. §112

The Examiner rejected claim 3 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants have amended claim 3 and it is believed that the amendment obviates the §112 rejection.

Rejection Under 35 U.S.C. §103(a)

Claims 1-6, 12-19 and 25-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Edwards et al. (USPN 5,472,441) in view of Edwards (USPN 5,836,906) in still further view of Swanson (USPN 6,267,760) and still in further view of Daniel et al. (USPN 7,008,421).

Regarding claims 1-6, 12-14 and 19 the Examiner states that Edwards discloses all of the claimed limitations except Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss and fail to explicitly disclose the step of making an incision into the tissue and advancing the application and extending the tissue-piercing distal tips along an incision line. Finally, the Examiner states that Edwards et al. fail to explicitly disclose bloodless resection of tissue.

The Examiner states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue. The Examiner further states that Daniel et al. disclose a device very similar to that of Edwards and teach the method of heating the tissue sufficiently with the needles in order to bloodlessly resect tissue. The Examiner concludes by stating at the time of the invention it would have been obvious to one of ordinary skill in the art to

modify the invention of Edwards et al, as taught by Edwards, and as taught by Swanson and as taught by Daniel et al.

With regard to claim 37, the Examiner states that Edwards et al. disclose all of the limitations of the claims but fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss, fail to disclose microwave (although Applicants' claims are not limited to microwave energy), fail to disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line and fail to disclose bloodless resection of tissue. The Examiner states that Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue. The Examiner further states that Daniel et al. disclose a device very similar to that of Edwards and teach the method of heating the tissue sufficiently with the needles in order to bloodlessly resect tissue. The Examiner concludes by stating therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al, as taught by Edwards, and as taught by Swanson and as taught by Daniel et al.

Applicants traverse the rejections and respectfully request reconsideration. The Examiner states that Daniel et al. is used to teach the "bloodless resection of tissue." Applicants have amended independent claims 1, 3 and 37 to cancel the bloodless resection of tissue and substitute "severing tissue without excessive bleeding" which has support in Applicant's originally filed August 4, 1998 application. Therefore, Applicants believe Daniel et al. is not prior art to the claims, as amended.

With regard to independent claims 1, 3 and 37 Applicants submit that none of the cited references, alone or in combination, teach or suggest a method of severing tissue from the body without excessive bleeding by creating a heat-treated tissue volume centered on a planned incision line, applying electromagnetic energy along the planned incision line, advancing the applicator along the planned incision line in step-wise manner and severing the tissue by incision along the planned incision line. The Examiner admits that Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss, fail to disclose the step of making an incision into the tissue which has been treated, advancing the applicator and extending the tissue-piercing needles into the tissue. Applicants respectfully suggest that Edwards et al. also fails to disclose

severing tissue from the body by incision along a planned incision line without excessive bleeding and neither Edwards '906 nor Swanson completes the combination. Edwards '906 simply discloses a device similar to Edwards et al. without any mention of a method of severing tissue from the body without excessive bleeding by creating a heat-treated tissue volume centered on a planned incision line, applying electromagnetic energy along the planned incision line, advancing the applicator along the planned incision line in step-wise manner, and severing the tissue from the body by incision along the planned incision line without excessive bleeding. Nor does Swanson make the disclosure required to complete the combination.

The Examiner uses Swanson for the disclosure on col. 8, lines 33-41.

In order to reduce the blood loss associated certain surgical procedures, a surgical method in accordance with another of the present inventions includes the steps of coagulating soft tissue and then forming an incision in the coagulated tissue. If the incision is no deeper than the coagulation, the incision will not result in significant bleeding. This process can be repeated until an incision of the desired depth is achieved.

However, to accomplish this Swanson discloses a blunt-tipped probe that is placed on or adjacent tissue to deliver energy. See, e.g. FIG. 71A. The probe of Swanson is not advanced into and does not pierce the tissue to be treated. Because Swanson is trying to avoid having the tissue bleed prior to incision, Swanson would not use the "tissue-piercing needles" of Edwards et al. and therefore one of ordinary skill in the art would not be motivated to modify Edwards et al. with the device or method of Swanson. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there can be no suggestion or motivation to make the proposed modification. MPEP 2143.02V. The device of Edwards et al. is intended to pierce healthy tissue and reach tumors that lie below the surface of such healthy tissue. The needles pierce the tumor and ablating energy is applied to the tumor in order to shrink or destroy it. "The device penetrates normal tissue to reach the tissue including the neoplasm and delivers therapeutic ablative energy to the tissue and/or deliver therapeutic substances to the tissue. It limits delivery of the therapeutic treatment to the precise location selected." Edwards et al. col. 1, lines 20-24. If the Edwards et al. device were modified with the blunt-tipped Swanson device, it would not be able to pierce tissue and would render it unsatisfactory for its intended purpose. Applicants propose that the combination of Edwards et al. and Swanson taken as a whole would not suggest the presently claimed invention to one of

ordinary skill in the art at the time the invention was made. Further, the claimed invention taken as a whole is not rendered obvious by the combination of Edwards et al., Edwards '906 and Swanson.

Both Edwards et al and Swanson et al. teach away from the combination. Edwards et al. teach that needle piercing tips are required so that they can penetrate healthy tissue to reach a cancerous tumor. Swanson et al. teach using a blunt tipped probe so that tissue is not pierced so that it does not bleed. "A reference teaches away from a combination when using it in that combination would produce an inoperative result." *In re ICON Health & Fitness, Inc.*, No. 06-1573 (Fed. Cir. 2007).

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See *United States v. Adams*, 383 U.S. 39, 52, 86 S.Ct. 708, 714, 15 L.Ed.2d 572, 148 USPQ 479, 484 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness"); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51, 220 USPQ 303, 311 (Fed.Cir.1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references taken in combination teach away since they would produce a "seemingly inoperative device"); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (CCPA1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant).

In re Francis S. Gurley, 27 F.3d 551, 31 USPQ2d 1130 (Fed. Cir. 1994).

Applicants respectfully suggest that the line of development flowing from using needles with tissue-piercing means and advancing the tissue-piercing means into tissue as disclosed by Edwards et al. in combination with a blunt-tipped probe for delivering energy into tissue is unlikely to be productive of the result sought by the Applicant. Moreover, modifying Edwards et al. with the device and method of Swanson would produce an inoperable result and therefore such a theoretical combination does not make the invention claimed in claims 1, 3, and 37

obvious. Because the combination of prior art references discourages the modification suggested by the Examiner, Edwards cannot be combined with Swanson.

Applicants respectfully suggest that claims 1, 3 and 37 are allowable over the art of record and because the dependent claims depend from allowable base claims, Applicant respectfully suggest that they too are allowable. MPEP §2143.03.

Conclusion

All rejections having been addressed Applicant earnestly solicits a Notice of Allowance in this case. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. Applicant hereby petitions for a three-month extension of time, the statutory period for response having expired on February 3, 2009 and this response being filed on or before the three-month extension period of May 4, 2009 (May 3 being a Sunday). Applicant hereby authorizes the Commissioner to charge the three-month extension of time fee to Deposit Account No. 50-1901 (Reference #22413-14).

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Respectfully submitted,

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